REMARKS

With this amendment, claims 17, 19, 21, and 45-56 are pending and currently under examination as corresponding to the elected claims in the present application. A response to the Restriction Requirement is presented below. Appendix A provides the "Version with Markings to Show Changes Made." For the Examiner's convenience, Appendix B provides all pending claims currently under examination.

The Invention

In one aspect, the present application provides, for the first time, isolated nucleotide and amino acid sequences of Slo3, a new potassium channel with novel functional properties. Although Slo3 is a member of the Slo family, to which the large-conductance, calcium-activated Slo1 potassium channel belongs, Slo3 channels are not gated by calcium. Slo3 channels, however, are activated by changes in intracellular pH and membrane potential, and are abundantly expressed in spermatocytes. Slo3 channels also exhibit markedly lower selectivity for K^+ over Na^+ than most voltage-gated K^+ channels.

Status of the Claims

Claims 45, 50 and 55 have been added to recite a molecular weight. These claims add no new matter. Support can be found, e.g., in the claims as filed and in the specification on page 10, lines 23-25.

Claims 46, 51, and 56 have been added to recite a homomeric channel. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 15, lines 20-23.

Claims 48, 49, 53, and 54 have been added. These claims add no new matter. Support for these claims can be found in the claims as originally filed.

Claims 47 and 52 have been added to recite stringent hybridization conditions. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 24, lines 8-14.

Response to Restriction Requirement

In response to the Restriction Requirement mailed June 29, 2001, Applicants elect to prosecute Group III, claims 17, 19, and 21, directed to a purified Slo3 polypeptide having structural features of an amino acid sequence of SEQ ID NO:16. New claims 45-56 also correspond to the elected group.

The foregoing election is made with traverse, as claims 1, 3, 5, 7, 9, 11-14, 16, 17, 19, 21, 24-30, 32, and 34 were placed in more than one group. For example, independent claim 17, claiming Slo3 polypeptides, was placed in Groups I-IV, as were dependent claims 19 and 21. However, the claims encompass orthologous and allelic sequences of the same gene or its encoded protein. Applicants, as described below, were the first to isolate the Slo3 gene and its corresponding protein, and are therefore entitled to claims that encompass a genus of Slo3 sequences, including orthologous and allelic sequences.

As such, on its face this rejection is improper and should be withdrawn. By placing claims 17, 19, and 21 (Groups I-IV); claims 1, 3, 7, 9, 11-14, 16, and 26-27 (Groups V-VIII); claims 22-25 (Groups IX-XII); and claims 28-30, 32, and 34 (Groups XIII-XVI); in more than one group, the Examiner has improperly attempted both to reject these claims for misjoinder, and to reject the claims on the basis that they allegedly represent independent and distinct inventions. Furthermore, examining the claims together would not place an undue examination burden on the Examiner, as the divided subject matter all fall within the same class and subclass. Each of claims 17, 19, and 21 (Groups I-IV); claims 1, 3, 7, 9, 11-14, 16, and 26-27 (Groups V-VIII); claims 22-25 (Groups IX-XII); and claims 28-30, 32, and 34 (Groups XIII-XVI), respectively, should therefore be examined together without restriction.

A. An Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions

By restricting a single claim and placing it in more than one group, the Examiner is alleging that the single claim represents multiple "patentably distinct" inventions. As such, this type of restriction requirement is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it

> may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder and Boksay,* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also In re Haas,* 179 USPQ 623, 624-625 (C.C.P.A. 1973) (*In re Haas I*); and *In re Haas,* 198 USPQ 334, 334-337 (C.C.P.A. 1978) (*In re Haas II*). *See also* MPEP § 803.02.

Moreover, it has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See In re Weber,* 198 USPQ at 328. The courts have definitively ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See id.*; *In re Haas I,* 179 USPQ at 623; and *In re Haas II,* 198 USPQ at 334. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no matter how broad, which means no matter how many independently patentable inventions may fall within it.
> *In re Weber,* 198 USPQ at 334.

As described above, the claims are directed to Slo3, a newly isolated gene and its encoded protein. This genus of nucleic acids and encoded proteins is claimed on the basis of common structural and functional features. Although the individual species of the genus may also be separately patentable, the genus as a whole represents a single invention. Therefore, rejecting claims 17, 19, and 21 (Groups I-IV); claims 1, 3, 7, 9, 11-14, 16, and 26-27 (Groups V-VIII); claims 22-25 (Groups IX-XII); and claims 28-30, 32, and 34 (Groups XIII-XVI), respectively, for misjoinder is therefore clearly improper. Applicants thus respectfully request that the Examiner

withdraw the improper restriction requirement with respect to Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively.

B. Examining the claims of Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively, together does not place an undue examination burden on the Examiner

Furthermore, restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. MPEP § 803.01. Applicants respectfully submit that examining the claims of Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively, would not place and undue burden on the Examiner.

In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner must show one of the following, as set forth in MPEP § 808.02:

> (1) *Separate classification thereof*:
> This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.
>
> (2) *A separate status in the art when they are classifiable together*:
> Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.
>
> (3) *A different field of search*:
> Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.
> Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

In the present case, Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively, are all classified in the same class and subclass. Applicants submit that searching Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively, together would place no undue burden on the Examiner. For example, Groups I-IV, corresponding to claims directed to Slo3 polypeptides, were all placed in the same class (530) and subclass (350). Applicants therefore respectfully request that the restriction requirement with respect to Groups I-IV, V-VIII, IX-XII, and XIII-XVI, respectively, and in particular with respect to Groups I-IV, be withdrawn.

Response to Sequence Listing Requirement

Applicants had previously submitted a copy of the Communication under 37 C.F.R. §§ 1.821-1.825 and Preliminary Amendment with a paper copy of the Sequence Listing from the parent application, along with a Statement under 37 C.F.R. § 1.821(e), at the initial filing of this divisional application. A copy is herewith provided again for the Examiner's convenience.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

17. (once amended) An isolated polypeptide monomer of a pH sensitive potassium channel, the monomer:

[(i) having a calculated molecular weight of between 120-156 kDa;]

[(ii)] (i) having a unit conductance of approximately 80-120 pS when the monomer is in a functional tetrameric form of a potassium channel and is expressed in a *Xenopus* oocyte;

[(iii)] (ii) having increased activity above approximately intracellular pH of 7.1; and

[(iv)] (iii) specifically binding to polyclonal antibodies generated against SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:16 OR SEQ ID NO:18.

19. (once amended) An isolated monomer of claim 17, wherein the monomer has an amino acid sequence of [hSlo3] human or mouse Slo3.

21. (once amended) An isolated monomer of claim 17, wherein the monomer has an amino acid sequence of SEQ ID NO:1, SEQ ID NO:16 or SEQ ID NO:18.

APPENDIX B

PENDING CLAIMS

17. (once amended) An isolated polypeptide monomer of a pH sensitive potassium channel, the monomer:

(i) having a unit conductance of approximately 80-120 pS when the monomer is in a functional tetrameric form of a potassium channel and is expressed in a *Xenopus* oocyte;

(ii) having increased activity above approximately intracellular pH of 7.1; and

(iii) specifically binding to polyclonal antibodies generated against SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:16 OR SEQ ID NO:18.

19. (once amended) An isolated monomer of claim 17, wherein the monomer has an amino acid sequence of human or mouse Slo3.

21. (once amended) An isolated monomer of claim 17, wherein the monomer has an amino acid sequence of SEQ ID NO:1, SEQ ID NO:16 or SEQ ID NO:18.

45. (new) An isolated monomer of claim 17, wherein the monomer has a calculated molecular weight of about 126 kDa.

46. (new) An isolated monomer of claim 17, wherein the monomer is a subunit of a homomeric potassium channel.

47. (new) An isolated polypeptide monomer of a pH sensitive potassium channel, the monomer:

(i) having a unit conductance of approximately 80-120 pS when the monomer is in a functional tetrameric form of a potassium channel and is expressed in a *Xenopus* oocyte;

(ii) having increased activity above approximately intracellular pH of 7.1; and

(iii) encoded by a nucleic acid that specifically binds under stringent hybridization conditions to a nucleic acid encoding an amino acid sequence of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:16 or SEQ ID NO:18, wherein the hybridization reaction is incubated at 42°C in a buffer

comprising 50% formamide, 5x SSC, and 1% SDS, and washed at 65°C in a buffer comprising 0.2x SSC and 0.1% SDS.

48. (new) An isolated monomer of claim 47, wherein the monomer has an amino acid sequence of human or mouse Slo3.

49. (new) An isolated monomer of claim 47, wherein the monomer has an amino acid sequence of SEQ ID NO:1, SEQ ID NO:16 or SEQ ID NO:18.

50. (new) An isolated monomer of claim 47, wherein the monomer has a calculated molecular weight of about 126 kDa.

51. (new) An isolated monomer of claim 47, wherein the monomer is a subunit of a homomeric potassium channel.

52. (new) An isolated polypeptide monomer of a pH sensitive potassium channel, the monomer:

(i) having a unit conductance of approximately 80-120 pS when the monomer is in a functional tetrameric form of a potassium channel and is expressed in a *Xenopus* oocyte;

(ii) having increased activity above approximately intracellular pH of 7.1; and

(iii) encoded by a nucleic acid that specifically binds under stringent hybridization conditions to a nucleic acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:17 or SEQ ID NO:19, wherein the hybridization reaction is incubated at 37°C in a buffer comprising 40% formamide, 1M NaCl, and 1% SDS, and washed at 45°C in a buffer comprising 1x SSC.

53. (new) An isolated monomer of claim 52, wherein the monomer has an amino acid sequence of human or mouse Slo3.

54. (new) An isolated monomer of claim 52, wherein the monomer has an amino acid sequence of SEQ ID NO:1, SEQ ID NO:16 or SEQ ID NO:18.

55. (new) An isolated monomer of claim 52, wherein the monomer has a calculated molecular weight of about 126 kDa.

56. (new) An isolated monomer of claim 52, wherein the monomer is a subunit of a homomeric potassium channel.